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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,210	03/17/2005	Stephen R. Smith	3323	9149

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EXAMINER	
GOUGH, TIFFANY MAUREEN	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)	
	10/528,210	SMITH ET AL.	
	Examiner	Art Unit	
	Tiffany M. Gough	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-22 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/28/2005.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,21 and their dependent claims are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of gastrointestinal infection in livestock does not reasonably provide enablement for prevention of gastrointestinal infection in livestock. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The claims encompass numerous gastrointestinal infections in livestock. Given the absolute meaning of prevention, an absolute stop to such encompassed infections, one of ordinary skill in the art would not be absolutely sure that any and all gastrointestinal infections will be prevented in view of the numerous conditions having a widely varying causative agents, encompassed by the claims. Thus, with the exception of treating infections such as necrotic enteritis and diarrheal disease, one of ordinary skill in the art would expect to undertake a trial and error process to determine which of the many infections encompassed by the claims would actually be able to be absolutely prevented, clearly amounting to undue experimentation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unilever PLC (EP 0466244 A1, 1992) in view of Medipharm (EP 0955061 A1,1999), Ibrahim (Natural food antimicrobial system, 2000) and Nippon (JP 62145025, 1987).

Applicant claims an antimicrobial composition used as an agent to suppress the growth of enteric pathogens such as *Clostridium perfringens, Escherichia coli, Salmonella typhimurium and Salmonella mbandaka*, either in powdered or aqueous solution or water-soluble form comprising a cell wall lysing substance or salt such as lysozyme, dried egg powder or albumen and a sequestering agent such as an organic

acid or a metal chelator which is administered to feedstock as a feed additive to prevent and treat gastrointestinal infections such as necrotic enteritis and diarrheal disease in livestock. Applicant claims the composition ratio of such composition being 2:5:3 by weight. Further applicant claims the use of dried egg powder in such composition is capable of suppressing microbes such as molds and viruses and also enzymes like proteases and lipases in livestock gut. Further, applicant claims cell wall lysing substance or salt, dried egg powder or albumen, a sequestering agent and a lantibiotic such as nisin, whose ratio in composition is 50:150:50:20.

Unilever PLC (EP 0466244 A1, 1992) disclose a mixture of the cell wall lysing substance lysozyme, antibacterial/lantibiotic nisin and the sequestering agent citric acid or another food-grade adjuvant, effectively preventing the growth of *Listeria monocytogenes* and also other microorganisms such as lactic acid bacteria which is used in connection with suppression of microorganisms in production, packaging and storage of food products, animal feeds, cosmetics and pharmaceutical products (see abstract). They disclose the effectiveness of using lysozyme in combination with citric acid or EDTA and other chelators or an antimycotic such as Pimaricine™ in foods to inhibit *Listeria monocytogenes*, bacteria and yeasts (see pg. 2 "Use of lysozyme" section). Unilever discloses a strong synergism existing between the action of lysozyme, nisin and citric acid (EDTA or salts thereof can be substituted for citric acid). These three ingredients used together effectively prevent the growth of many strains of bacteria and are much more effective when used in combination than when used alone (see pg. 3 "Brief summary of invention and detailed description" paragraphs). They also

suggest that antimycotics such a Pimaricine™ , which suppress the growth of molds and yeasts, can be used in combination with such mixture and further suggest that at least one antibacterial compound must be present in the synergistic composition (pg. 4 lines 20-24). Thus Unilever's invention is a composition, which has improved antibacterial properties, comprising a mixture of at least one representative of each group (a) a cell wall lysing substance (b) an antibacterial compound and (c) and adjuvant such as an organic acid or sequestering agent and further claims the following ratio of such composition (a) 5-2000 mg : (b) 5 x 10^3 -5 x 10^6 IU : (c) 0.5-100 g.

Unilever differs from the claims in that their composition is not disclosed as containing egg powder or albumen and further to suppress the growth of enteric pathogens, specifically *Clostridium sp. , E.coli* and *Salmonella sp.* However, Medipharm (EP 0955061 A1,1999) discloses an oral product for the prevention and therapy of porcine gastroenteric infections, more specifically directed towards the rotavirus, coronaviruses and enteropathogenic and enterotoxigenic bacterial strains of *Clostridium sp. , E.coli* and *Salmonella sp.* The oral compositions raw material is liquid eggs, which are freeze-dried resulting in a powder form product, from which antibodies are obtained. The product exists in a paste, water-soluble powder formula which may be mixed with water, and a powder formula (see pg. 3 "Principle of invention" section).

Further support of the why one would use egg or albumin in an antimicrobial composition is provided by Ibrahim (Natural food antimicrobial system, 2000). Ibrahim discloses that an avian egg is one of many natural antimicrobial systems available. Egg whites, also known as albumin, is the eggs second line of defense against bacteria after

the shell and membranes. The proteins in egg whites are thought to prevent invasion of microorganisms into the yolk and most posses antimicrobial properties which hinder the growth and spread of microorganisms. Such antimicrobial properties include lysozyme, which hydrolyzes the peptidoglycan of bacterial cell walls, ovotransferrin, which chelates metal ions, vitamin binding proteins and proteinase inhibitors (see introduction). Even further support is Nippon (JP 62145025, 1987) disclosing an antiviral agent containing albumen as an active component for the suppression of viruses such as rotavirus (see abstract).

One of ordinary skill in the art would therefore have been motivated by Ibrahim's disclosure of the antimicrobial properties eggs possess and to apply this knowledge to the composition in Medipharms application used for the prevention and therapy of porcine gastroenteric infections, more specifically directed towards the rotavirus, coronaviruses and enteropathogenic and enterotoxigenic bacterial strains of *Clostridium sp.* , *E.coli* and *Salmonella sp.* and to further apply these advantages to the composition disclosed by Unilever containing a mixture of the cell wall lysing substance lysozyme, antibacterial/lantibiotic nisin and the sequestering agent citric acid or another food-grade adjuvant, effectively preventing the growth of *Listeria monocytogenes* and also other microorganisms such as lactic acid bacteria which is used in connection with suppression of microorganisms in production, packaging and storage of food products, animal feeds, cosmetics and pharmaceutical products.

With respect to the composition ratios in claims 10,16 and 22, optimizing the ratio as disclosed by Unilever is practiced through routine scientific experimentation. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."). See MPEP 2144.05

Thus the claimed invention as a whole is prima facie obvious over the prior art.

Conclusion

No claims are found allowable over the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tiffany M. Gough whose telephone number is 571-272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tmg